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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,177	05/02/2002	Ingrid Jochmus	50125/036001	1172

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EXAMINER	
SALIMI, ALI REZA	
ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 08/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/980,177	Applicant(s) Jochmus et al
	Examiner A. R. SALMI	Art Unit 1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *Three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jul 11, 2003* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *28-60* is/are pending in the application.

4a) Of the above, claim(s) *29-31 and 39-58* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *28, 32-38, 59, and 60* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on *May 2, 2002* is/are a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *13*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Response to Amendment

This is a response to the amendment C, paper No.18, filed 7/11/2003. Claims 59, and 60 have been added. Claims 28-60 are pending.

Election/Restriction

Applicant's election with traverse of Group II (Claims 28, 32-38, 59, and 60 within the scope of ICWGNQLFV SEQ ID NO: 12) in Paper No. 18 is acknowledged. The traversal is on the ground(s) that the reference cited by the Office does not disclose cytotoxic T-cell epitope as newly amended claim 28 requires. Applicants assert the claims as currently amended belong to a single general inventive concept under PCT Rule 13.1, and neither the restriction or election requirement is justified. This is not found persuasive because the claimed invention is directed to a product, irrespective of its function, and the same product is taught and was well known in the art as disclosed by de Gruijl (1999), as a consequence applicants' invention does not make a contribution over the prior art. Thus, the claims are not so linked by a special technical feature within the meaning of PCT Rule 13.2 as such the restriction is proper.

The requirement is still deemed proper and is therefore made FINAL.

Claims 29, 30, 31, 39-58 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected groups, the requirement having been traversed in Paper No. 18.

The claims have been examined only to the extent of selected polypeptide designated as SEQ ID NO: 12. Applicants are requested to amend the claim accordingly by canceling the non-elected polypeptides.

Applicants are reminded to cancel the claims to the non elected claims.

Claim Rejections - 35 USC § 112

Claims 28, 32-38, 59, and 60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 28 is vague and indefinite for recitation of "functionally active variant thereof", first "active" is a relative terminology, and is subject to varied interpretation. In addition, the intended "functionally active variant thereof" are not defined, the intended metes and bounds of the "functionally active variant thereof" are not defined. Moreover, claim 28 is indefinite for

recitation of "having" this is open language, it is not clear what other polypeptides are present or how long the intended polypeptide maybe. This affects the dependent claims.

Claim 32 is vague and indefinite, the intended "compound" is not defined. Is aspirin intended to be the compound? This affects the dependent claims.

Claim 33 is vague and indefinite, the intended metes and bounds of the polypeptide is not defined.

Claims 34-37 are vague and indefinite, the intended polypeptide(s) is/are not defined. The intended polypeptide(s) should be identified by a specific sequence identification number.

Claims 36, 59 are objected to for recitation of "approx.", please spell out the entire word. Is approximately intended?

Claims 59 and 60 are vague, indefinite and unclear for recitation of"homology", and " at least approx. 65%, ...75%...., 85%." The claims have been interpreted in view of the specification and it not clear what sequences are encompassed that at least have 65%, 75%, 85% identity. Identity, homology or sequence similarity can be calculated by a variety of different methods, whereby the calculated identity between two sequences will be quite different depending on the algorithm used for calculation. Applicant has referred to various % "homology", but there are no indication of the utilized algorithm to calculate the identity sequences. Furthermore, the calculation of "identity" is affected by variables such as the relative weight given to the sequence

gaps versus mismatches, or whether conservative substitutions are weighted differently from non-conservative substitutions. In addition, "homology" is attributed to sequences which share a common evolutionary history, or in other words, if there existed an ancestral molecule in the past that was ancestral to both of the sequences. The claims do not set forth any sequences having common evolutionary history.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a **written description** of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 28, 32-38, 59, and 60 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are broadly drawn to multitude of "homologous" sequences, functionally active variants thereof, "compounds", and/or polypeptides of various sizes. In contrast, the specification describes sequence consisting of a sequence identified as SEQ ID NO: 12. Applicants do not describe other molecules encompassed by the claims, and the structural features that distinguish all such proteins from other proteins. Applicants were not in possession and no description is provided of the sequences that fall within

the limitations of the claims that are now present. Hence, Applicants have not, in fact, described the molecules that are within the full scope of the claims, and the specification fails to provide an adequate written description of the claimed invention.

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed general sequence, it is not clear the Applicant was in possession of the genus claimed at the time this application was filed.

See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed, Cir. 1997):

> The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA .... Accordingly, the specification does not provide a written description of the invention ....

and at pg 1406:

> a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicted, does not suffice to define the genus because it is only an indication of what the genes does, not what it is.

See *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at page 1021:

> A gene is a chemical compound, albeit a complex one, and ... conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials .... Conception does not occur unless one has a mental picture of the structure of the chemical or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by it principal biological property, *e.g.*, encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 28, 32, 33, 36-38, 59, and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Dillner et al (WO 90/04790).

The teaching and claims of the above cited reference anticipates the broad limitations of the claimed invention. Dillner et al taught the polypeptide of SEQ ID NO: 12 as now being claimed (see page 30, line 34, and page 29 Table 3, "Pep No. 24"). In addition, thy taught the labeling of the products as well (see page 24, lines 2-5). The product disclosed in

the above cited reference appears to be identical to the product claimed by the applicants. Applicants are reminded that the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products. Moreover, if the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Claims 28, 32-38, 59, and 60 are rejected under 35 U.S.C. 102(b) as being anticipated by Chan et al (Journal of Virology, Oct. 1992, Vol. 66, No. 10, pp. 5714-5725).

According to the in-house sequence search the sequence having accession number M96299 as part of human papillomavirus type 56 (HPV-56) meets the broad limitations of the claimed invention.The product disclosed in the above cited reference appears to be identical to the product claimed by the applicants. Applicants are reminded that the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products. Moreover, if the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Claims 28, 32, 33, 36-38, 59, and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Dillner et al (US Patent No. 5,629,146).

The teaching and claims of the above cited reference anticipates the broad limitations of the claimed invention. Dillner et al taught the polypeptide of SEQ ID NO: 12 as now being claimed (see all claims especially claim 2). The product disclosed in the above cited reference appears to be identical to the product claimed by the applicants. Applicants are reminded that the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products. Moreover, if the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 28, 32-38, 59, and 60 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Frazer et al (WO 93/02184). Frazer et al taught overlapping peptides of HPV-16 L1 protein to produce specific immune response. The product that is being claimed by the applicants' claimed invention is disclosed in the above cited reference (see Table 1, No. 35, 36, 37). Alternatively, one of ordinary skill in the art at the time of filing would have been motivated to fuse two or more of the recited polypeptides of Table 1 to be able to induce specific immune response. One of ordinary skill in the art being familiar with the above cited art would not have anticipated any unexpected results, as none have been provided, since the epitopes are already disclosed. Hence, the claimed invention as a whole is prima facie obvious absent unexpected results.

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (703) 305-7136. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is (703) 305-3014, or (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

A. R. Salimi

8/5/2003